

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

THIS DOCUMENTS RELATES TO:  
ALL ACTIONS

MDL 1456

Master File No. 01-CV-12257-PBS

Judge Patti B. Saris

**IMMUNEX CORPORATION'S ANSWER TO  
PLAINTIFFS' FOURTH AMENDED MASTER CONSOLIDATED  
CLASS ACTION COMPLAINT**

Defendant Immunex Corporation ("Immunex") answers the Fourth Amended Master Consolidated Class Action Complaint ("FAMCC"), dated March 1, 2006, and the Notice of Errata to the FAMCC, dated March 10, 2006, as follows:

The FAMCC improperly and repetitively refers to Immunex and other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Immunex.

Immunex was acquired by defendant Amgen Inc. during this litigation, but remains separately incorporated. Immunex is not responsible for the actions of Amgen, and Amgen is not responsible for the actions of Immunex. Amgen has assumed the marketing of Enbrel, and it will answer as to Enbrel and all Enbrel-related activities.

Intentionally ambiguous pleading is improper and insufficient to apprise Immunex in any meaningful sense of the allegations asserted against it. Immunex has nevertheless attempted to respond to Plaintiffs' allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct, or actions of other defendants or entities, Immunex is without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Immunex denies those allegations. Immunex answers Plaintiffs' allegations on behalf of itself only, even when Plaintiffs' allegations refer to alleged conduct by Immunex and other persons or entities. The FAMCC improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations in the FAMCC are vague or conclusory. The FAMCC also includes terms that are undefined and susceptible to different meanings. By addressing factual allegations and not pointing out each and every ambiguity or challenging every innuendo or conclusion, Immunex does not admit any of Plaintiffs' interpretations or conclusions. To save space, Immunex will not repeat the above and similar caveats each time they apply.

The FAMCC contains purported quotations from a number of sources, many of which are unidentified. Referencing or purporting to summarize a potential item of evidence is not an allegation and does not require an answer. In responding to allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote was or was not true at the time the document was created, much less before or after its creation, or that the material is relevant or admissible in this action.

Immunex denies each and every allegation contained in the FAMCC, except as specifically admitted, and any factual allegation admitted is admitted only as to the specific

facts and not as to any conclusions, characterizations, implications, innuendo, or speculation contained in or suggested by any allegation or the FAMCC as a whole. Moreover, Immunex specifically denies any allegations contained in headings, footnotes, the Table of Contents, Appendices, and unnumbered paragraphs in the FAMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer. Immunex numbers its answering paragraphs below to reflect the relevant paragraph or paragraphs in the FAMCC.

1. Immunex admits that Plaintiffs purport to bring this alleged class action against Immunex and other pharmaceutical companies but otherwise denies each other or different allegation of Paragraph 1. Immunex denies that Plaintiffs are entitled to maintain this action in the manner alleged.

2. Immunex denies the existence of, or its participation in, any "conspiracy" as alleged in Paragraph 2. To the extent the allegations in Paragraph 2 allege a conspiracy between Immunex and "various publishing entities," no response is required because these allegations, which formed the basis of Count I of the Amended Master Consolidated Complaint, were dismissed with prejudice by the Court's Order dated February 24, 2004.

3 – 4. As to Paragraphs 3 – 4, Immunex admits that it has manufactured or distributed certain medicines that are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that it reports some pricing information for its medicines to independent pharmaceutical industry publications. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by

providers. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex, Immunex denies those allegations.

5. Immunex admits that AWP is used by certain payors as a benchmark for reimbursement outside of Medicare. To the extent that any remaining allegations in Paragraph 5 are directed at Immunex, Immunex denies those allegations.

6. Immunex admits that Plaintiffs purport to bring this action as alleged in Paragraph 6, but Immunex denies that Plaintiffs are entitled to maintain this action in the manner alleged. Immunex denies that it "promotes" its drugs on a "fictitious and inflated AWP." Except as specifically admitted and to the extent that the remaining allegations in Paragraph 6 are directed at Immunex, Immunex denies those allegations.

7. Immunex denies the existence of, or its participation in, any "high profit scheme" as alleged in Paragraph 7. Immunex denies that it has "concealed" information regarding the pricing structure for its prescription drugs. To the extent that any remaining allegations in Paragraph 7 are directed at Immunex, Immunex denies those allegations.

8. Immunex admits that Plaintiffs have filed attachments to the FAMCC. Except as specifically admitted and to the extent the allegations in Paragraph 8 are deemed to include allegations against Immunex, Immunex denies them.

9. Immunex admits that this Court has subject matter jurisdiction, subject to the political question doctrine and other defenses raised below. Upon information and belief, Immunex admits that this Court has diversity jurisdiction. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 9 are directed at Immunex and require a response, Immunex denies those allegations.

10. Immunex admits the allegations in Paragraph 10.

11. Immunex admits that venue is proper in this jurisdiction for purposes of the pretrial proceedings as alleged by Plaintiffs in Paragraph 11, but Immunex denies that venue is proper in this jurisdiction for trial or other non-MDL purposes. Immunex denies the existence of, and its participation in, any "fraudulent marketing scheme" as alleged in Paragraph 11. To the extent that the remaining allegations in Paragraph 11 are directed at Immunex and require a response, Immunex denies those allegations.

12. Immunex admits the allegations in Paragraph 12.

13. To the extent that the allegations in Paragraph 13 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

14 – 17. To the extent that the allegations in Paragraphs 14 – 17 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

18. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 18, and therefore denies those allegations.

19 – 20. To the extent that the allegations in Paragraphs 19 – 20 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

21. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 21, and therefore denies those allegations.

22 – 24. To the extent that the allegations in Paragraphs 22 – 24 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

25 – 27. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraphs 25 – 27 and therefore denies those allegations.

28 – 29. To the extent that the allegations in Paragraphs 28 – 29 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

30. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 30, and therefore denies those allegations.

31. To the extent that the allegations in Paragraph 31 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

32. Immunex admits that Plaintiffs propose UFCW as a representative for Class 3.

33. To the extent that the allegations in Paragraph 33 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

34. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 34, and therefore denies those allegations.

35 – 37. To the extent that the allegations in Paragraphs 35 – 37 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

38. Immunex admits that BCBSMA is a proposed representative for Class 3 against Track 1 defendants. Immunex is without information sufficient to form a belief concerning the accuracy of the remaining allegations in Paragraph 38, and therefore denies those allegations.

39 – 39a. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraphs 39 – 39a, and therefore denies those allegations.

40 – 62. To the extent that the allegations in Paragraphs 40 – 62 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of the allegations, and therefore denies those allegations.

63 – 67. Immunex admits that Plaintiffs VPIRG, WCA, StateWide, CANY, and CCJ purport to bring this action as alleged in Paragraphs 63 – 67, but Immunex denies that these Plaintiffs have standing to bring the alleged action. Immunex is without information sufficient to form a belief concerning the accuracy of the remaining allegations in Paragraphs 63 – 67, and therefore denies those allegations.

68 – 69. Immunex denies the existence of, or its participation in, any "conspiracy" as alleged in Paragraph 69. Immunex denies the remaining allegations in Paragraphs 68 – 69 that pertain to it.

70 – 117. To the extent that any allegations in Paragraphs 70 – 117 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of those allegations, and therefore denies those allegations.

118. Immunex admits that it became a wholly-owned subsidiary of Amgen Inc. during the pendency of this litigation and that its principal place of business as of the commencement of the action is Seattle, Washington. Immunex admits that it developed products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. Immunex's Annual Reports speak for themselves. Except as specifically admitted, Immunex denies the remaining allegations in Paragraph 118.

119. Immunex admits that it manufactured and distributed pharmaceuticals that were administered by Medicare Part B providers in most if not all states. Immunex admits that, at various points in time, it manufactured or distributed leucovorin calcium, Enbrel®, Novantrone®, Leukine®, and Thioplex®. Immunex denies the remaining allegations in Paragraph 119.

120. Immunex admits that it was acquired by Amgen in July 2002. Immunex denies the remaining allegations in Paragraph 120.

121 – 144. To the extent that any allegations in Paragraphs 121 – 144 are deemed to include allegations against Immunex, Immunex is without information sufficient to form a belief concerning the accuracy of those allegations, and therefore denies those allegations.

145. To the extent that any allegations in Paragraph 145 are deemed to include allegations against Immunex, Immunex denies those allegations.

146. Upon information and belief, Immunex admits the allegations in Paragraph 146.

147. Immunex admits that the Medicare Part B program and other payors used AWP as a reimbursement benchmark. Immunex denies the remaining allegations in Paragraph 147 that pertain to it.

148. Immunex admits that there are several independently produced pharmaceutical industry compendia that periodically publish AWPs and other reimbursement benchmarks and prices. Immunex denies the remaining allegations in Paragraph 148 that pertain to it.

149. Immunex denies any allegations in Paragraph 149 that pertain to it.

150 – 154. Immunex denies the existence of, and its participation in, any "scheme to generate the profit spread" or any "AWP scheme" as alleged in Paragraphs 150 – 154. Immunex denies the remaining allegations in Paragraphs 150 – 154 that pertain to it.

155 – 157. The allegations in Paragraphs 155 – 157 state legal conclusions to which no response is required. To the extent a response is required, Immunex denies any allegations in Paragraphs 155 – 157 that pertain to it.

158. Immunex admits that 42 C.F.R. § 405.517 sets forth the reimbursement methodology for drugs covered by Medicare Part B and is the best evidence of its contents. Immunex is without information sufficient to form a belief concerning the accuracy of the remaining allegations in Paragraph 158 and therefore denies those allegations.

159 – 160. Immunex denies the allegations in the first sentence of Paragraph 159 insofar as it contains material in quotation marks the source of which is not identified. Immunex denies the second sentence of Paragraph 159 insofar as 42 C.F.R. § 405.517 contains no reference to a "ceiling" on reimbursement amounts. Immunex admits that 42 C.F.R. § 405.517 was amended on January 1, 1998, to "provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP." Immunex denies the remaining allegations in Paragraphs 159 – 160 that pertain to it.

161. Immunex admits that the Medicare Program had publicly announced its use of the AWP as a reimbursement benchmark. Immunex states that Program Memo AB-99-63 cited in Paragraph 161 is the best evidence of its contents. Immunex denies the remaining allegations in Paragraph 161 that pertain to it.

162. Immunex states that Program Memo AB-99-63 cited in Paragraph 162 is the best evidence of its contents. Immunex denies the remaining allegations in Paragraph 162 that pertain to it.

163. The allegations in Paragraph 163 state legal conclusions to which no response is required. To the extent a response is required, Immunex denies any allegations in Paragraph 163 that pertain to it.

164. Immunex admits the allegations in Paragraph 164.

165. Immunex admits that it reported certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex denies the remaining allegations in Paragraph 165 that pertain to it.

166 –167. The April 2003 OIG Guidance cited in Paragraphs 166 –167 is the best evidence of its contents, but Immunex does not admit that the contents were accurate when created or of any legal effect. Immunex denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion from the Guidance, or that such are applicable to Immunex or are retroactive. Immunex denies the remaining allegations in Paragraphs 166 – 167 that pertain to it.

168. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies the remaining allegations in Paragraph 168 that pertain to it.

169 – 170. Immunex denies the existence of, and its participation in, any "scheme" cited in Paragraph 169. Immunex states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 169 – 170 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have

accurately characterized the findings, opinions, statements, or conclusions of Congressman Stark, or that such are applicable to Immunex. Immunex denies the remaining allegations in Paragraphs 169 – 170 that pertain to it.

171. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies the remaining allegations in Paragraph 171 that pertain to it.

172. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 172. Immunex denies the remaining allegations in Paragraph 172 that pertain to it.

173. Immunex admits that on occasion prior to July 1995 it provided suggested AWPs for its medicines to independent pharmaceutical industry publications. Immunex denies the remaining allegations in Paragraph 173 that pertain to it.

174 – 197. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 176. Immunex denies the remaining allegations in Paragraphs 174 – 197 that pertain to it.

198. Immunex admits that Plaintiffs purport to quote from an unidentified "industry consultant" in Paragraph 198, but Immunex denies any allegations suggested by the quoted material. Immunex denies the remaining allegations in Paragraphs 198 that pertain to it.

199. Immunex denies the allegations in Paragraph 199 that pertain to it.

200. Immunex states that the *Red Book* and the unidentified DOJ report cited in Paragraph 200 are the best evidence of their contents, but does not admit that the contents were accurate when created. To the extent the allegations in Paragraph 200 include allegations against Immunex, Immunex denies them.

201. Immunex denies the allegations in Paragraph 201 that pertain to it.

202 – 203. Immunex states that the pleadings cited in Paragraphs 202 – 203 and subparts are the best evidence of their contents, but does not admit that the contents were accurate when created. To the extent the allegations in Paragraphs 202 – 203 and subparts are deemed to include allegations against Immunex, Immunex denies them.

204. Immunex denies the allegations in Paragraph 204 that pertain to it.

205. Immunex states that the 2003 CMS document cited in Paragraph 205 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement, or conclusion. Immunex admits that it sold its medicines in competitive markets and, as such, took steps to keep certain information relating to its medicines confidential. Immunex denies the remaining allegations in Paragraph 205 that pertain to it.

206 – 209. Immunex denies any allegations in Paragraphs 206 – 209 that pertain to it.

210. In response to the allegations in Paragraph 210, Immunex denies that Plaintiffs lacked inquiry or other notice of the issues associated with reliance on AWPs as a reimbursement benchmark. Immunex specifically alleges, to the contrary, that such issues were well-known for more than a decade before Plaintiffs elected to bring this suit.

211 – 212. The allegations in Paragraphs 211 – 212 state legal conclusions to which no response is required. To the extent a response is required, Immunex denies any allegations in Paragraphs 211 – 212 that pertain to it.

213. Immunex denies any allegations in Paragraph 213 that pertain to it.

214 – 404. The allegations in Paragraphs 214 – 404 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 214 – 404 are deemed to include allegations against Immunex, Immunex denies them.

405. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 405. Immunex denies that it has stated "fraudulent AWPs." Immunex denies that Plaintiffs are entitled to judgment or any relief and denies any other allegations in Paragraph 405 that pertain to it.

406. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 406. Immunex admits that the governmental agencies listed in Paragraph 406 have conducted investigations concerning pricing in the pharmaceutical industry and that Immunex has received and responded to requests for information from these agencies. Immunex denies the remaining allegations in Paragraph 406.

407. Immunex states that the "internal document" cited in Paragraph 407 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the conclusions Plaintiffs have drawn from the document cited in Paragraph 407 are accurate and denies the remaining allegations in Paragraph 407.

408. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported class period. Immunex admits that on occasion prior to July 1995 it reported suggested AWPs to independent pharmaceutical industry publications. Immunex states that the October 26, 2000, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized the letter. Immunex states that the interview cited in document IAWP003071 is the best evidence of its contents, but does not admit that the contents were accurate when

created. Immunex denies that the conclusions Plaintiffs have drawn from the documents cited in Paragraph 408 are accurate and denies the remaining allegations in Paragraph 408.

409. Immunex states that the January 12, 1996, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex states that the January 12, 1995, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported class period. Immunex admits that on occasion prior to July 1995 it reported suggested AWPs to independent pharmaceutical industry publications. Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 409 and denies the remaining allegations in Paragraph 409.

410. Immunex admits that it understood that AWP was a reimbursement benchmark. Immunex states that "internal documents" IAWP012961 and IAWP051149-52 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 410 and denies the remaining allegations in Paragraph 410 and its subparts.

411. Immunex states that the February 21, 1997, memo is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 411 and denies the remaining allegations in Paragraph 411.

412. Immunex states that documents IAWP003407-13 and IAWP016686-88 are the best evidence of their contents, but does not admit that the contents were accurate when

created. Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 412 and denies the remaining allegations in Paragraph 412.

413. Immunex states that document IAWP005418 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the document. Immunex denies all remaining allegations in Paragraph 413.

414. Immunex admits that it distributed methotrexate sodium and leucovorin calcium during part of 2001 and that the AWP reimbursement benchmark for the drugs might have been higher than the actual prices paid by some customers of wholesalers. Immunex states that the DHHS Report cited in Paragraph 414 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized the DHHS Report and denies the remaining allegations in Paragraph 414.

415. Immunex admits that it distributed Novantrone® in 1997 and that the AWP reimbursement benchmark for the drug was higher than the actual prices that might have been paid by some customers of wholesalers. Immunex states that the DHHS 1997 Report is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized the DHHS 1997 Report and denies the remaining allegations in Paragraph 415.

416. Immunex admits that it produced documents pursuant to government requests. Immunex admits that Plaintiffs have reviewed such documents and that each such document is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized such

documents or that such conclusions Plaintiffs have drawn are accurate and denies the remaining allegations in Paragraph 416.

417. Immunex denies the allegations in Paragraph 417.

418. Immunex states that document IAWP016524 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the document cited in Paragraph 418 and denies the remaining allegations in Paragraph 418.

419 – 501. The allegations in Paragraphs 419 – 501 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 419 – 501 are deemed to include allegations against Immunex, Immunex denies them.

502. Immunex denies the allegations in Paragraph 502 that pertain to it.

503 – 506. Immunex admits that Plaintiffs purport to bring this action as alleged in Paragraphs 503 – 506, but Immunex denies that Plaintiffs are entitled to maintain this action in the manner alleged. Immunex denies the remaining allegations in Paragraphs 503 – 506 that pertain to it.

507 – 511. The allegations in Paragraphs 507 – 511 state legal conclusions to which no answer is required. Immunex denies, however, that Plaintiffs have pled a proper class or named proper class representatives. To the extent that an answer to Paragraphs 507 – 511 is required, Immunex denies those allegations.

512. The allegations in Paragraph 512 state legal conclusions to which no answer is required. Immunex denies, however, that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraph 512. To the extent that an answer to Paragraph 512 is required, Immunex denies those allegations.

513 – 541. The Court dismissed Count I in its Order dated February 24, 2004. Accordingly, Immunex does not respond to Paragraphs 513 – 541 of the FAMCC. To the extent a response is required, Immunex denies all allegations contained within Count I of the FAMCC.

542. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 541 in answering Paragraph 542.

543. Immunex admits that Plaintiffs purport to bring this action and to seek relief under Count II of the FAMCC as alleged in Paragraph 543, but Immunex denies that Plaintiffs are entitled to maintain this action as alleged. Immunex denies that Plaintiffs are entitled to any relief against Immunex under Count II of the FAMCC. Immunex denies any remaining allegations in Paragraph 543.

544. The allegations in Paragraph 544 state a legal conclusion to which no answer is required. Immunex denies, however, that Plaintiffs have pled a proper class.

545. To the extent the allegations in Paragraph 545 and its subparts state legal conclusions, no answer is required. Immunex is without knowledge or information sufficient to form a belief as to the accuracy of the remaining allegations in Paragraph 545 and subparts, and therefore denies those allegations.

546 – 550. Immunex denies the existence of, or its participation in, any "enterprise," "criminal purposes," "AWP Scheme," or "hidden profit-making scheme" as alleged in Paragraphs 546 – 550. Immunex states that the unidentified "industry report" cited in Paragraph 550 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized any alleged "industry report" finding, opinion, statement or conclusion. Immunex denies any remaining allegations in Paragraphs 546 – 550 that pertain to it.

551 – 573. Immunex denies the existence of, or its participation in, any "enterprise," "AWP Scheme," "The Immunex Manufacturer-PBM Enterprise" and/or "Manufacturer-PBM Enterprise" as alleged in Paragraphs 551 – 573 and their subparts. Immunex denies any existence of, or its participation in any operation or conduct for "criminal purposes" as alleged in Paragraph 556(k). To the extent the allegations in Paragraphs 551 – 573 and their subparts include any allegations against Immunex, Immunex denies them.

574. The allegations in Paragraph 574 state legal conclusions to which no response is required. To the extent a response is required, Immunex denies the allegations in Paragraph 574.

575. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 574 in answering Paragraph 575. Immunex denies the remaining allegations in Paragraph 575.

576. The allegations in Paragraph 576 state legal conclusions to which no response is required. To the extent a response is required, Immunex denies that Plaintiffs have standing to bring this action, and denies that an actual case and controversy exists. Immunex denies that setting stated reimbursement prices above the actual average wholesale price for AWPIDs is unlawful and denies any remaining allegations in Paragraph 576 that pertain to it.

577 – 578. Immunex realleges and incorporates its responses to the allegations in Paragraph 576 in answering the first sentence of Paragraph 577. Immunex denies that it "exploit[ed] the Medicare reimbursement system." Immunex denies the remaining allegations in Paragraphs 577 – 578 that pertain to it. If the Court determines a legally enforceable definition of AWP that varies from historical practice, that definition should be prospective only.

579. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 578 in answering Paragraph 579. Immunex denies the remaining allegations in Paragraph 579.

580. Immunex admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the FAMCC as alleged in Paragraph 580, but Immunex denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Immunex under Count IV. Immunex denies the remaining allegations in Paragraph 580.

581. Immunex admits that its principal place of business at the commencement of this action is Seattle, Washington. Immunex admits that certain states have enacted consumer protection laws, but Immunex denies that such laws apply, that it has violated such laws, or that Plaintiffs or any putative class members are entitled to relief under such laws. Immunex denies any remaining allegations in Paragraph 581 and subparts that pertain to it.

582 – 586. Immunex denies the existence of, and its participation in, any "AWP Scheme" as alleged in Paragraph 582. Immunex denies any remaining allegations in Paragraphs 582 – 586 and subparts that pertain to it. Immunex further denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 582 – 586.

587. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 586 in answering Paragraph 587. Immunex denies the remaining allegations in Paragraph 587.

588. Immunex admits that Plaintiffs purport to bring this action and to seek relief under Count V of the FAMCC as alleged in Paragraph 588, but Immunex denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Immunex under Count V. Immunex denies the remaining allegations in Paragraph 588.

589. The allegations in Paragraph 589 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraph 589 are deemed to include allegations against Immunex, Immunex denies them.

590 – 591. Immunex admits that Plaintiffs purport to bring this action and to seek relief under Count V of the FAMCC as alleged in Paragraphs 590 – 591, but Immunex denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Immunex under Count V. Immunex denies the remaining allegations in Paragraphs 590 – 591.

592. Immunex denies the allegations in Paragraph 592 that pertain to it.

593. Immunex admits that certain states have enacted consumer protection laws, but Immunex denies that such laws apply, that it has violated such laws, or that Plaintiffs or any putative class members are entitled to relief under such laws. Immunex denies any remaining allegations in Paragraph 593 and subparts that pertain to it.

594 – 595. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraphs 594 – 595 and therefore denies those allegations.

596. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 595 in answering Paragraph 596. Immunex denies the remaining allegations in Paragraph 596.

597 – 599. Immunex admits that Plaintiffs purport to bring this action and to seek relief under Count VI of the FAMCC as alleged in Paragraphs 597 – 599, but Immunex denies that Plaintiffs are entitled to maintain this action as alleged or to any relief against Immunex under Count VI. Immunex denies the remaining allegations in Paragraphs 597 – 599.

600. Immunex denies the allegations in Paragraph 600 that pertain to it.

601. Immunex admits that certain states have enacted consumer protection laws, but Immunex denies that such laws apply, that it has violated such laws, or that Plaintiffs or any putative class members are entitled to relief under such laws. Immunex denies any remaining allegations in Paragraph 601 and subparts that pertain to it.

602 – 603. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraphs 602 – 603 and therefore denies those allegations.

604. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 603 in answering Paragraph 604. Immunex denies the remaining allegations in Paragraph 604.

605 – 613. The allegations in Count VII, as alleged in Paragraphs 605 – 613 appear to be directed to other defendants and require no response from Immunex. To the extent allegations in Paragraph 605 – 613 are deemed to include allegations against Immunex, Immunex denies them.

614 – 621. Count IX and the allegations in Paragraphs 614 – 621 are brought only by Plaintiff CMHV, which does not allege that it purchased any Immunex product and require no response from Immunex. To the extent allegations in Paragraphs 614 – 621 are deemed to include allegations against Immunex, Immunex denies them. In particular, Immunex denies the existence of, and its participation in, any "scheme," "AWP Scheme," "conspiracy" or "The Immunex Manufacturer-PBM Conspiracies."

## DEFENSES

Without assuming any burden that it would not otherwise have, and without waiving any denial above, Immunex further responds to the FAMCC by alleging the following:

1. The Complaint fails to state a claim upon which relief may be granted.
2. Immunex has not acted in a manner that is illegal, oppressive, or fraudulent and in fact acted in good faith, with just cause, and in accordance with established industry practices and government requirements and policies.
3. The federal government adopted AWP as a reimbursement benchmark with knowledge that it was not a calculation of actual average prices and with no express or implicit definition contrary to industry practice. For public policy and other reasons, the federal government retained AWP as a reimbursement benchmark in the face of years of criticism that it was not a calculation of actual average prices. Among the defenses that arise from those and other relevant circumstances are the following:
  - A. Plaintiffs' claims are barred, in whole or in part, by the political question, separation of powers, and filed rate doctrines. The relief sought by Plaintiffs would interfere with legislative decisions and functions.
  - B. Plaintiffs' claims are barred, in whole or in part, because Immunex has complied with all applicable statutes and regulations.
  - C. Plaintiffs' claims are barred, in whole or in part, because they violate Immunex's rights under the Due Process and Ex Post Facto Clauses of the United States Constitution, as well as all applicable state constitutions, insofar, among other things, as Plaintiffs and the putative class members

seek to impose liability under vague or nonexistent standards or retroactively for conduct that was not actionable at the time it occurred.

D. Plaintiffs' claims are barred, in whole or in part, because Immunex did not make any false statements to Plaintiffs or to any members of the putative class. Immunex had no reasonable grounds to believe, and did not believe, that any statement was false or misleading or capable of being false or misleading.

E. The communications and conduct of Immunex and others are protected by the First Amendment, applicable state constitutions, and common law privileges, and it would violate those protections to construe the AWP practice and term of art as fraudulent.

F. Plaintiffs' claims are barred, in whole or in part, by the government contractor and similar defenses because the reimbursement system, including the use of AWP in excess of actual average prices, was designed and approved by the United States Government to serve its purposes.

G. Immunex relied on the policies and practices of the federal and state governments, and plaintiffs are estopped or otherwise barred from seeking to impose liability for such reliance.

H. Plaintiffs' approach to AWP would discourage legitimate price competition and is inconsistent with and preempted by the Sherman Act.

I. Plaintiffs' claims are barred, in whole or in part, because, *inter alia*, in directly or indirectly adopting "AWP" outside of its government reimbursement and industry context Plaintiffs acted recklessly and assumed all risks that they or their representatives might not understand it properly,

because they are bound by the government's knowledge and purposes, and because they consented to and ratified use of AWP.

J. Plaintiffs' and the putative class' claims are barred because Immunex did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

4. Plaintiffs' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, regulations promulgated under those acts, and by the dormant Commerce Clause of the United States Constitution.
5. Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or expressive conduct by Immunex, healthcare providers, or others directed at judicial, legislative, or administrative bodies of government.
6. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and repose.
7. Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.
8. Plaintiffs lack standing and privity.
9. Immunex denies that Plaintiffs and the putative class have met the statutory and case law requirements of state consumer protection acts. However, if such claims are found to exist, Immunex pleads all available defenses under

the Acts, including standing, lack of direct purchaser, federal preemption, and lack of consumer status or involvement.

10. Plaintiffs' claims for declaratory or equitable relief are barred because plaintiffs have an adequate remedy at law, because the claims were rendered moot by the passage of the 2003 Medicare reform legislation, and due to the doctrine of *in pari delicto* or unclean hands.
11. Plaintiffs' claims are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price because third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums or in other ways; because such supracompetitive price, if any, was absorbed, in whole or part, by a person or entity that purchased the medicine directly, or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members; or because purchasers who paid directly or indirectly on the basis of an allegedly excessive AWP would have paid more with respect to this or other elements of health care pricing in the absence of AWP.
12. To the extent Plaintiffs or any member of the putative class obtain or have obtained recovery or have benefited from another entity's recovery in this or any other case or through any other method predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against Immunex based on the FAMCC.
13. Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction, or otherwise compromised their claims.

14. Plaintiffs' claims are barred, in whole or in part, due to their failure to join indispensable parties.
15. Plaintiffs' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties or of the Plaintiffs or their agents or representatives.
16. Plaintiffs' claims are barred, in whole or in part, because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.
17. Plaintiffs' claims are barred, in whole or in part, because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Immunex.
18. Plaintiffs' claims are barred, in whole or in part, because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the FAMCC.
19. Immunex is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs or the putative class, with respect to the same alleged injuries.
20. Any damages recovered by the Plaintiffs and the putative class from Immunex must be limited by any applicable statutory ceilings on recoverable damages.

21. Any punitive damages would be excessive, penal in nature, and subject Immunex to multiple and retroactive liability and deny Immunex constitutionally adequate standards, instructions, and procedures.
22. Plaintiffs' claims for punitive damages are barred by federal and state constitutions, common law, and public policies.
23. Maintenance of this action as a class action would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch.
24. Maintenance of this action as a class action and in one proceeding against many defendants would violate Immunex's rights as provided by the Federal and state constitutions by denying Immunex procedural and substantive safeguards.
25. Plaintiffs' claim for punitive and other damages against Immunex cannot be sustained because any award without the apportionment of the award separately and severally between or among the defendants and other alleged responsible parties, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Immunex's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable state.
26. Plaintiffs are not the real parties in interest.
27. Immunex maintained policies regarding samples, grants, and other issues that prohibited unlawful or questionable practices. Immunex regularly instructed relevant employees as to such policies. To the extent that

Immunex had knowledge of conduct that could be viewed as improper, Immunex took prompt and reasonable steps to correct and halt such conduct, including disciplinary action against employees.

28. Immunex's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.
29. Plaintiffs and the putative class fail to state with particularity facts to support the fraud or conspiracy allegations as required by Fed. R. Civ. P. 9(b), and fail to plead with particularity the fraudulent concealment and multi-source drug allegations against Immunex.
30. Plaintiffs' and the putative class' RICO claims against Immunex are barred, in whole or in part, due to Plaintiffs' failure to properly allege a RICO enterprise as required by 18 U.S.C. § 1962(c).
31. Plaintiffs' and the putative class' RICO claims against Immunex are barred, in whole or in part, due to Plaintiffs' failure to plead facts showing that Immunex and the PBMs are ongoing organizations whose members function as a continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981).
32. Plaintiffs' and the putative class' RICO claims against Immunex are barred, in whole or in part, due to Plaintiffs' failure to allege that Immunex conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).
33. Plaintiffs and the putative class lack standing to bring their RICO claims against Immunex because they cannot show Immunex directly caused their alleged injuries as required by 18 U.S.C. § 1964(c). *Holmes v. Securities*

*Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992); *Platten v. HG Berm. Exempted Ltd.*, 437 F.3d 118, 132 (1st Cir. 2006).

34. Plaintiffs' and the putative class' civil conspiracy claims against Immunex are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1<sup>st</sup> Cir. 1994) and *Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 359 (D. Mass. 2002), and by their failure to allege a coercive conspiracy as required by *Fleming v. Dance*, 22 N.E.2d 609, 611 (Mass. 1939).
35. Plaintiffs' and the putative class' civil conspiracy claims against Immunex are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. *See Grant*, 183 F. Supp. 2d at 364.
36. Plaintiffs and the putative class fail to allege facts or a cause of action against Immunex sufficient to support a claim for attorneys' fees, treble damages or legal fees.
37. Plaintiffs' and the putative class members' claims are barred, in whole or in part, because they conflict with federal statutes and regulations that comprise a comprehensive regulatory regime governing the amounts paid to providers for Medicare Part B-covered drugs.
38. Plaintiffs and the putative class members are barred from recovery because the representations and actions alleged by Plaintiffs were not and are not material, in that they were not and are not likely to affect the decisions or conduct of Plaintiffs and putative class members, or to have caused consumers or Third Party Payors to have chosen differently, but for such alleged representations or actions, in light of the information available and

known to consumers and Third Party Payors, and in that the alleged representations and actions were not likely to mislead consumers or Third Party Payors acting reasonably under the circumstances.

39. Plaintiffs' and the putative class members' claims fail, in whole or in part, because of improper claim splitting.
40. Plaintiffs' and the putative class members' claims against Immunex are barred, in whole or in part, by the doctrines of assumption of risk, comparative fault, and negligence.
41. Immunex adopts by reference any additional applicable defense pled by any other defendant not otherwise pled in this answer. Immunex hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Immunex also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part of it, is governed by the substantive law of a state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, and Washington.

#### **PRAYER FOR RELIEF**

WHEREFORE, Defendant Immunex Corporation requests the following relief:

- A. Dismissal of Plaintiffs' claims with prejudice;
- B. An award of attorneys' fees and costs; and
- C. Such other legal and equitable relief as the Court deems proper.

DATED this 15th day of May, 2006.

/s/ Kathleen M. O'Sullivan

David J. Burman

Kathleen M. O'Sullivan

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IMMUNEX CORPORATION

**CERTIFICATE OF SERVICE**

I hereby certify that on May 15, 2006, I caused a true and correct copy of Immunex Corporation's Answer to Plaintiffs' Fourth Amended Master Consolidated Class Action Complaint to be served on all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending a copy to LexisNexis File and Service for posting and notification to all parties.

By /s/ Kathleen M. O'Sullivan  
Kathleen M. O'Sullivan